IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	MDL No. 19-2875 (RBK)

SPECIAL MASTER ORDER NO. __

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3 (the "Motion to Seal") filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S. Inc., and Solco Healthcare US, LLC (collectively, "the ZHP Parties" or "ZHP") on notice to liaison counsel for Plaintiffs; and the Court having considered the Parties' submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth therein have not been met, the Court makes the following Findings of Fact and Conclusions of Law:

1. "[I]n cases involving large-scale discovery, the court may construct a broad umbrella protective order upon a threshold showing by the movant of good cause." *In re Avandia Mktg., Sales, and Prods. Liab. Litig.*, 924 F.3d 662, 671 n.5

(3d Cir. 2019) (quoting *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 787 n.17 (3d Cir. 1994)). "However, Courts must be vigilant to assure Confidentiality Orders are not overused and are only used for legitimate purposes." *In re Valsartan N-Nitrosodimethylamine (NDMA), Losartan, and Irbesartan Prods. Liab. Litig.*, 512 F. Supp. 3d 546, 550 (D.N.J. 2021). This Court has previously noted that "the purpose of entering a protective order is not to insulate a party from the annoyance, embarrassment, oppression, or burden that may be caused by having to defend claims of wrongdoing the details of which appear in materials produced during discovery." *Id.* (emphasis added).

2. ZHP carries the burden on this motion. When a party challenges a designation under an umbrella protective order, "the party seeking to maintain the seal must justify the continued sealing of those documents." *Avandia*, 924 F. 3d at 671 n.5 (quoting *Pansy*, 23 F.3d at 787 n.17).

3. ZHP contends that the existence of an umbrella confidentiality order somehow "weighs in favor" of its designations, (ECF 2459-1, p. 5), but umbrella confidentiality orders are intended to facilitate discovery, and once a specific designation is challenged, "the district court must conduct a document-by-document review" based on the applicable factors, depending on whether the documents are still unfiled discovery or have become court records. *Avandia*, 924 F. 3d at 671 n.5 (emphasis added). Crucially, the designating party bears the burden

of proof the entire time. *Id.* ZHP's current motion concerns its own expert report from a chemist explaining why it bears no liability for the claims in this MDL. The umbrella confidentiality order is consequently irrelevant to whether that report should be shielded from public view.

4. "In *Pansy v. Stroudsburg*, 23 F. 3d 772 (3rd Cir. 1994), the court expounded on the burden to justify confidentiality." *Valsartan*, 512 F. Supp. 3d at 550. There, the Third Circuit set forth seven factors to consider when deciding a motion to seal:

> 1. whether disclosure will violate any privacy interests;
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> 2. whether the information is being sought for a legitimate purpose or for an improper purpose;
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> 3. whether disclosure of the information will cause a party embarrassment;
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> 4. whether confidentiality is being sought over information important to public health and safety;
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> 5. whether the sharing of information among litigants will promote fairness and efficiency;
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> 6. whether a party benefitting from the order of confidentiality is a public entity or official; and
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> 7. whether the case involves issues important to the public.

Avandia, 924 F.3d at 671 (emphasis added) (quoting *Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995) (citing *Pansy*, 23 F.3d at 787-91)); *see also, e.g.*, ECF 1269, p. 6-7. Importantly, this standard applies "when [a court] review[s]

orders preserving the confidentiality of discovery materials pursuant to Federal Rule of Civil Procedure 26." *Avandia*, 924 F.3d at 670 (citing *Pansy*, 26 F.3d at 783-92); *see also, e.g.*, ECF 1269, p. 7. All of these factors cut against ZHP, which has the heavy burden on this motion.

5. "[T]he more rigorous common law right of access [applies] when discovery materials are filed as court documents. In addition to recognizing fewer reasons to justify the sealing of court records, the public right of access—unlike a Rule 26 inquiry—begins with a presumption in favor of public access." *Avandia*, 924 F.3d at 670 (emphasis added) (citing *Goldstein v. Forbes (In re Cendant Corp.)*, 260 F.3d 183, 192–93 (3d Cir. 2001)); *see also, e.g.*, ECF 1269, p. 7.

> The common law right of access "antedates the Constitution." *Bank of Am. Nat'l Tr. & Sav. Ass'n v. Hotel Rittenhouse Assocs.*, 800 F.2d [339,] 343 [(3d Cir. 1986)]. The right of access "promotes public confidence in the judicial system by enhancing testimonial trustworthiness and the quality of justice dispensed by the court." *Littlejohn v. BIC Corp.*, 851 F.2d 673, 678 (3d Cir. 1988). Public observation facilitated by the right of access "diminishes possibilities for injustice, incompetence, perjury, and fraud." *Id.* Moreover, "the very openness of the process should provide the public with a more complete understanding of the judicial system and a better perception of its fairness." *Id.*

Avandia, 924 F.3d at 672. Thus, once a document "has been filed with the court ... or otherwise somehow incorporated or integrated into a district court's adjudicatory proceedings," "a presumption of access attaches." *Id.* (emphasis added) (quoting *In*

re Cendant Corp., 260 F.3d at 192); *see also, e.g.*, ECF 1269, p. 8.

6. "To overcome that strong presumption, the District Court must articulate 'the compelling, countervailing interests to be protected,' make 'specific findings on the record concerning the effects of disclosure'….'" *Avandia*, 924 F.3d at 672-73 (quoting *In re Cendant Corp.*, 260 F.3d at 194); *see also, e.g.*, ECF 1269, p. 8. "In delineating the injury to be prevented, specificity is essential," so "[b]road allegations of harm, bereft of specific examples or articulated reasoning, are insufficient." *Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194) (emphasis added); *see also, e.g.*, ECF 1269, p. 8. In sum, "[c]areful factfinding and balancing of competing interests is required before the strong presumption of openness can be overcome by the secrecy interests of private litigants." *Avandia*, 924 F.3d at 673 (emphasis added) (quoting *Leucadia, Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 167 (3d Cir. 1993)); *see also, e.g.*, ECF 1269, p. 8. ZHP's motion is built on broad allegations of harm, nothing more—there is insufficient information submitted on this motion for the Court to make the findings necessary to find in ZHP's favor.

7. Moreover, although some of the seven *Pansy* factors are relevant to a court's analysis under the common law standard, two are explicitly not considered. *Id.* at 677. First, the Third Circuit has "repeatedly said that concern about a company's public image, embarrassment, or reputational injury, without more, is

insufficient to rebut the presumption of public access." *Id.* (emphasis added) (collecting cases). Second, "a person's motive for inspecting or copying judicial records is irrelevant under the common law right of access." *Id.* at 677.

8. The Third Circuit has put its "thumb on the scale in favor of openness—the strong presumption of public access" in exactly this situation:

> [T]he public's right of access must be the starting point, not just one of multiple factors. The scale is tipped at the outset in favor of access. And the right of access is not a mere formality—it "promotes public confidence in the judicial system"; "diminishes possibilities for injustice, incompetence, perjury, and fraud"; and "provide[s] the public with a more complete understanding of the judicial system and a better perception of its fairness." *Littlejohn*, 851 F.2d at 678. These interests are particularly important in a case such as this one, which implicates the public's trust in a well-known and (formerly) widely-used drug.

Avandia, 924 F. 3d at 677 (emphasis added). Moreover, "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm." *Id.* at 678 (quoting *In re Cendant Corp.*, 260 F.3d at 196) (emphasis added). That showing cannot be made by ZHP since the extensive cGMP failures and related misunderstanding of basic chemistry causing the contamination are a matter of public record, and the failed manufacturing processes at issue are banned. Moreover, the two defunct processes and ZHP's current manufacturing processes are all subject to patents protecting any limited

interests ZHP still has. (Exs. 1-3).[1] In other words, at this point, we are looking back at a cautionary tale, one that every regulator and responsible scientist and physician has already agreed should never happen again. Moreover, "blanket assertions of harm that 'could' come to fruition fall short of the clearly defined and serious injury that [a movant] must articulate to obtain sealing under any standard." *Id.* at 679. As discussed below, ZHP fails that test, and cannot meet it with regard to presumptively public documentation of the facts surrounding its wholesale contamination of a trusted blood pressure drug using defunct manufacturing process.

9. On remand from the Third Circuit in *Avandia*, the trial court unsealed "55 documents—including clinical studies, *GSK submissions to the FDA*, internal GSK emails and letters, records of teleconferences between GSK and the FDA, Avandia presentations and plans, and some court filings in the MDL," with the exception of "certain personal information that Plaintiffs do not object to redacting." *In re Avandia Mktg, Sales Practices and Prods. Liab. Litig.*, 484 F. Supp. 3d 249, 264-68 (E.D. Pa. 2020) (emphasis added). At the same time, the court denied the defendants' motion to seal over a half a dozen expert reports and declarations. *Id.* at 255, 262-264, 268. The court summarized its decision in the following manner:

[1] Unless otherwise noted, all exhibits referenced in this brief are attached to the Certification of Adam M. Slater in Support of Plaintiffs' Opposition to ZHP's Motion.

> Justice Brandeis famously declared that "sunlight is the most powerful of all disinfectants." Considering the common law presumption of public access, the lack of harm GSK will face, the significance of this litigation, and the number of people affected, light must shine on these documents. Therefore, for the reasons stated above, GSK's Motion for the Continued Sealing of Certain Documents will be granted only as to the redaction of personal information of study subjects and employee telephone numbers, addresses, and the ending of email addresses and otherwise denied, and GSK's Motion for the Continued Sealing of the Expert Reports of Donald Austin, Eliot Brinton, and Brian Swirsky will be denied.

Id. at 268 (emphasis added). The court reaches the same conclusion here.

10. Of great significance here, in one of its prior confidentiality rulings in this case, the Court noted that it "is not required to give credence to [a] conclusory self-serving affidavit that is inconsistent with the Court's independent review of [the] documents." *Valsartan*, 512 F. Supp. 3d at 553. The Court also rejected the argument that its decision was impacted because the authors or recipients expected the documents to remain confidential, explaining "[o]therwise, large swatches of routine emails would be kept under wraps." *Id.* This is in line with Judge Kugler's decision in *In re Forest Research Institute, Inc.*, No. 13–1845 (RBK/AMD), 2014 WL 12618100 (D.N.J. June 16, 2014) (Ex. 4). *See also* ECF 1911, at 12-14, 20; ECF 2405 (unsealing the 2018 EMA Inspection Report that ZHP argued was confidential when under the control of the EMA).. There, Judge Kugler denied an *unopposed* motion to seal, explaining that "[m]erely because a document is

designated 'confidential' does not necessarily mean that document satisfies the criteria for sealing." *Id.* at *2. He added that "even if the confidential nature of these documents did somehow satisfy the criteria for sealing, [movants] fail to explain the clearly defined and serious injury that would result if the relief sought is not granted." *Id.* *Centennial Mill by Del Webb Community Association, Inc. v. Ply Gem Holdings, Inc.* is also instructive on this issue, demonstrating that self-serving arguments are unavailing:

> In opposition to Plaintiff's Motion to Reman[d], to demonstrate the inapplicability of the forum selection clause, Defendants relied, in part, on the Confidential Documents, which include confidential settlement communications pertaining to the resolution of the Prior Lawsuit and the negotiation of the Settlement Agreement. Additional documents and discussion pertaining to settlement and negotiations were relied upon by Plaintiff in Reply.
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> Defendants argue disclosure of this information would "cause substantial harm to Defendants and impair their ability to defend against other claims of alleged 'Thermal Distortion.'" Defendants argue they have been sued, and may later be sued, in other matters relating to thermal distortion, and that "public access to the Confidential Documents will provide other/future claimants or co-defendants the opportunity to attempt to utilize the information therein in pursuit of liability claims against Defendants, and thus, such disclosure will impair Defendants' ability to effectively defend against other/future disputed claims."

No. 1:17–cv–7675 (NLH/JS), 2018 WL 3085210, at *5 (D.N.J. June 22, 2018) (Ex. 5). This description of harm far exceeds what ZHP has provided here. Yet, the

Court found that the defendants "failed to justify their Motion to Seal with regard to convincing this Court that there are 'legitimate private or public interest[s] which warrant the relief sought' and that 'clearly defined and serious injury ... would result if the relief sought is not granted.'" *Id.* (quoting Local Rule 5.3). The court explained:

> The Court has closely reviewed the documents Defendants ask the Court to seal and cannot discern a legitimate private or public interest warranting sealing, nor a serious injury that would result to Defendants. Defendants' index is not persuasive, as it does not state with particularity any harm that would result. Rather, Defendants' index broadly claims: "Public access to information concerning the alleged 'thermal distortion' in settlement communications and negotiation could disadvantage Defendants in other matters/litigations." Preliminarily, some of the information Defendants ask the Court to seal can be obtained, or easily inferred, from documents already publicly filed, such as the length of the settlement negotiations, that the state court litigation concerned the thermal distortion phenomenon, and the definition of thermal distortion.
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> However, even as to other information that might not be available to the public now, the Court does not find sufficient basis to seal. This Court has repeatedly emphasized the public interest in the disclosure of materials filed on this Court's docket, which often outweighs private interests in confidentiality. This Court is funded by the public and does not sit, in general, to resolve private disputes in secret. Finding Defendants lack a legitimate justification to warrant sealing the identified information, the Court will deny Defendants' Motion to Seal in full.

Id. at *5-6. Importantly, this MDL is not even a private dispute, something ZHP

somehow continues to imply in its briefing. (*See, e.g.*, ECF 2459-1, p. 12). It concerns hundreds of personal injury cases and class actions involving millions of class members, all related to the worldwide recall of Defendants' contaminated drugs. Unnamed class members are of particular importance now that class certification has been granted, and those unnamed class members will soon need to decide whether to be bound the outcome of the upcoming class actions trials. The expert report ZHP seeks to redact is one of the most important documents for someone to review before making that decision.

11. Thus, as this Court has previously held, an entity's mere designation of a document as confidential is irrelevant to whether it actually is confidential once it is filed with the Court. *Valsartan*, 512 F. Supp. 3d at 554; *Forest Research*, 2014 WL 12618100, at *2; *Centennial Mill*, 2018 WL 3085210, at *5-6. After all, it is the movant's burden to overcome the public's right to access and prove a document warrants sealing based on "the kind of information" contained in the document and a specific showing "that disclosure will work a clearly defined and serious injury to the party seeking closure." *Avandia*, 924 F.3d at 672; s*ee also, e.g.*, ECF 1269, p. 8.

ZHP Did Meet Its Burden

12. In this motion, ZHP has asked the Court to seal substantial portions of

its own expert's report attempting to exonerate it from liability in this case.[2] ZHP's brief concedes that the common law public right of access applies to the report, but then ignores this important fact throughout its legal analysis and in its proposed order for the Court's signature. (ECF 2459-1, p. 4; ECF 2459-7). *See also Avandia*, 924 F.3d at 672. In addition to "the strong presumption" in favor of the public's access to court records, and the fact that there is nothing sensitive about the documents on their face—certainly not at present, years after the events occurred and the processes banned from use—this Court recognizes the significant public interest in understanding the nitrosamine contamination at issue in this case. *Avandia*, 924 F. 3d 677-78. ZHP was the first pharmaceutical manufacturer to recall its drugs due to their contamination with carcinogenic nitrosamines, and the issue is not limited to valsartan, losartan, and irbesartan. FDA, *Recalls of Angiotensin II Receptor Blockers (ARBs) including Valsartan, Losartan and Irbesartan*, https://tinyurl.com/1k9w9jid; FDA, *Information about Nitrosamine Impurities in Medications*, https://tinyurl.com/1tu3nih0. There is an ongoing public investigation into the cause of this widespread contamination, whether it has occurred with other drugs, and how to prevent it in the future, on top of the FDA's

[2] The report is attached to the unredacted version of Plaintiff's *Daubert* Motion to Preclude the Opinions of Fengtian Xue as Exhibit 2, which was submitted to the Court for *in camera* review pursuant to the Court's umbrella confidentiality order. (ECF 2288).

firm determination that the contamination was wrongful and unacceptable, resulting in a complete recall and years-long import ban against ZHP. In fact, ZHP was banned from importing its valsartan into the United States because it could not address its cGMP violations to the satisfaction of the FDA for over three years. FDA, Warning Letter to ZHP (Nov. 28, 2018) (noting the "FDA placed your firm on Import Alert 66-40 on September 28, 2018"), https://tinyurl.com/mryxvt2p; FDA. Closeout Letter to ZHP (Nov. 4, 2021), https://tinyurl.com/36wfntf4.

13. The Court will not allow ZHP to shield its substantive defense to its otherwise universally recognized wrongdoing in this case from public scrutiny. ZHP has a history of using obfuscation as its primary public defense to the allegations here. *See* The Straits Times, *'Please pay attention': Scientist flagged heart-pill toxins early on* (May 8, 2022), https://tinyurl.com/4fjr9t35 (responding to the public disclosure of the July 27, 2017 email by stating "This email involves complex scientific issues that will be addressed by scientific experts in the valsartan litigation," and "This email was written in Chinese and highlights the difficulties associated with translating from the original language and culture."). Allowing ZHP to hide the details of its primary liability expert report would provide it with another opportunity to point to the publicly unknown details of the report to support its lack of responsibility for the contamination of its widely used valsartan. It would also prevent absent class members from assessing the merits of this case in deciding

whether to opt out or commit themselves to the outcome of this Court's proceedings. These types of concerns, among others, are why the *Avandia* trial court unsealed over a half a dozen expert reports and declarations. 484 F. Supp. 3d at 255, 262-264, 268.

14. Ignoring these concerns, ZHP repeats a mantra that the report contains information from its "confidential DMF filing with the FDA." (ECF 2459-1, p. 6; *see also id.* at 1, 2, 7, 8, 10, 13). However, this Court has repeatedly rejected the argument that a document's confidentiality prior to this case is relevant to its confidentiality after becoming a court record. *Forest Research*, 2014 WL 12618100 (Ex. 4); *see also* ECF 1911, at 12-14, 20; ECF 2405 (unsealing the 2018 EMA Inspection Report that ZHP argued was confidential when under the control of the EMA). This is especially true for ZHP's DMFs, which document nearly every aspect of its manufacture of valsartan. If the mere presence of information in a DMF rendered it confidential, nearly everything in this case would be confidential, which is clearly not the law.[3] Importantly, the excerpts ZHP seeks to seal are not even

[3] ZHP's first case regarding DMFs—*Amgen Inc. v. Zydus Pharms. (USA) Inc.*, No. 19-18806(MAS)(DEA), 2021 WL 2550449 (D.N.J. May 18, 2021)—involved an unopposed motion in a pharmaceutical patent case, where its extreme theory was obviously never litigated, as it has been here repeatedly. In the second case—*In re Gabapentin*, 312 F. Supp.2d 653, 669 (D.N.J. 2004)—the court denied an investment research company's motion to unseal summary judgment papers filed in pharmaceutical patent holder's infringement suit against prospective manufacturers of the generic version. In that case, the investment research company's entire purpose was to uncover information for the competitive benefit of others, and the

from ZHP's DMFs; they are from its August 26, 2018 response to the FDA's finding that it violated cGMPs when its inadequate change control system failed to detect the nitrosamines created in its original ZnCl2 process. ZHP may seek to minimize the importance of the information it seeks to seal, but the information is from its main response to the FDA concerning the nitrosamine contamination of its valsartan, and it was important enough to include in its primary liability expert report, which it decided to serve, knowing it would become a juridical record subject to the public's right of access, something that has been repeatedly litigated throughout this case.

15. To the extent it needs to protect any information concerning its valsartan manufacturing processes, ZHP can rely on it numerous public patents, which elaborate those processes in great detail in order to establish their exclusive rights to use those processes. For example, ZHP's first ZnCl2 patent discusses l-

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Court was clear that "parties set forth the specific nature of the trade secret information contained in the briefs including the ANDAs, Drug Master Files, formulations, testing of products, and Warner–Lambert's research and development history." *Id.* at 667. Thus, *Gabapentin* actually supports Plaintiffs' position and the Court's prior rulings in this case that the contents of the documents, not prior designations in other contexts, control whether something is confidential. ZHP cites another two unpublished and unopposed decisions regarding the confidentiality of ANDAs. (ECF 2459-1, p. 8-9 (*Valeant Pharms. Luxembourg S.a.r.l. v. Actavis Lab'ys UT, Inc.*, No. 16-04344(JLL)(JAD), 2018 WL 1832914 (D.N.J. Apr. 16, 2018); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharms. Inc.*, No. 14-4727 (NLH/KMW), 2015 WL 4715307 (D.N.J. Aug. 7, 2015)). The Court cannot follow these unpublished decisions from intra-industry litigation that raise none of the concerns present here.

valine, ethyl acetate, valeryl chloride, toluene, sodium carbonate, sodium hydroxide, DMF, zinc chloride (ZnCl2), sodium azide, methyl tertiary butyl ether (MTBE), and ethyl acetate. (*Compare with, e.g.,* Xue R. 23, 26-27, 34-36). A lot of the information ZHP seeks to redact for the ZnCl2 process does not even change from the unredacted information for the TEA process. (*See* Xue R. 23). The patent for ZHP's TEA process also discusses l-valine, ethyl acetate, hydrochloride, valeryl chloride, toluene, sodium azide, ethyl acetate, sodium bicarbonate, triethylamine hydrochloride, and hydrochloric acid. (*Compare with, e.g.,* Xue R. 23, 26-27, 34-36). Last, ZHP's patent for the post-recall ZnCl2 process discusses ethyl acetate, sodium chloride (NaCl), toluene, sodium hydroxide, DMF, zinc chloride (ZnCl2), sodium azide, sodium hydroxide, sodium nitrite, hydrochloric acid (HCl), triethylamine hydrochloride, magnesium sulfate, and hydrochloric acid. (*Compare with, e.g.,* Xue R. 23, 26-27, 34, 36). And the structures of these chemicals are public knowledge and easily found on Google, let alone in a chemistry textbook. Given the protection and public nature of these patents, both the public in general and absent class members have an overwhelming right to access the full report allegedly exonerating ZHP from any liability in this case.

16. ZHP's declaration in support of its motion does not address these arguments, which were discussed during the meet and confer preceding this motion. In fact, the declaration is from a former employee of ZHP who works for a

subsidiary not even involved in this litigation, and located in Hubei Province compared to ZHP's Zhejiang Province location. (Ex. 6). The name of the current employer does not even appear in any defendant's production in English nor in Chinese. Crucially, ZHP's motion must be based on current personal knowledge. Loc. R. 5.3(c)(3); 12/09/2020 Tr., 10:1-22 (stating, "I expect Torrent to produce with that in-camera inspection, a supporting affidavit, and then I will determine whether or not the confidentiality designation is appropriate or not. …. I've written a lot on this issue, an affidavit from an attorney is insufficient. An attorney doesn't have firsthand knowledge of what's required under the order, the discovery order that the Court entered. So if you submit a supporting affidavit signed by an attorney, I expect that your application will be denied quickly, but I would expect you to submit an affidavit from an appropriate knowledgeable person from your clients who has personal knowledge of the issues…." (emphasis added)); *In re Caterpillar Inc., C13 and C15 Engine Prods. Liab. Litig.*, MDL No. 2540, 2015 WL 12830520, at *3 (D.N.J. Jan. 29, 2015) (denying motion to seal that was supported by an affidavit without personal knowledge) (Ex. 7); *Schatz-Bernstein v. Keystone Food Prods., Inc.*, No. 08–3079–RMB–JS., 2009 WL 1044946, at *2 (D.N.J. Apr. 17, 2009) (same) (Ex. 8); *see also Avandia*, 924 F. 3d at 678 (holding that "[s]ealing must be based on *current evidence* to show how public dissemination of the pertinent materials *now* would cause the competitive harm." (quoting *In re*

Cendant Corp., 260 F.3d at 196) (emphasis added)). A declaration from a former employee who no longer works on anything involved in this case does not satisfy this requirement, warranting the denial of the motion on this basis alone.

17. The declarant's overarching argument is that "[t]he Redacted Information includes highly sensitive and detailed information regarding ZHP's manufacturing of Valsartan active pharmaceutical ingredient ("API"), including information regarding ZHP's *current manufacturing processes* for Valsartan APL" (ECF 2459-5, ¶ 6). This is an odd statement coming from someone who no longer works at ZHP, but it is also deceptive because it essentially admits that not all the redacted information is "current." However, the declarant does not bother to distinguish which information is current and which is not. This type of ambiguity is why a motion to seal must be specific, and ZHP's failure to provide that level of specificity requires denying the motion. *Avandia*, 924 F.3d at 673 (quoting *In re Cendant Corp.*, 260 F.3d at 194); *see also, e.g.*, ECF 1269, p. 8.

18. Importantly, the ZnCl2 process discussed in the proposed redactions is no longer used, as it contaminated the drug with nitrosamines, and the current ZnCl2 process is subject to its own patent. (Exs. 2-3). The declarant contends details of the original ZnCl2 "esterification step" and "acylation step" are "confidential" when the patent discusses esterification and nearly all the chemicals involved in the acylation step, and both of these steps have extremely limited changes, as shown in

the chart at issue. (ECF 2459-5, ¶ 7; Ex. 2, p. 2). ZHP also seeks to seal information regarding the condensation, crude product, purification, and unnamed steps, which the declarant does not even try to justify with any specificity. The Court consequently denies all of these proposed redactions.

19. The declaration's remaining paragraphs similarly elide the distinction between the original ZnCl2 process and the current one, again raising questions of her personal knowledge of ZHP's current operations. (ECF 2459-5, ¶ 8-10). As discussed above, ZHP's patents discuss the most sensitive and innovative parts of this process in great detail, and the public and absent class members have a right to understand and fully evaluate ZHP's attempt to exonerate itself from any liability in this case. The Court cannot accept ZHP's conclusory attempt to override that right. *See Avandia*, 484 F. Supp. 3d at 255, 262-264, 268 (denying the defendants' motion to seal over a half a dozen expert reports and declarations); *see also Valsartan*, 512 F. Supp. 3d at 553 (noting that the Court "is not required to give credence to [a] conclusory self-serving affidavit").

Pursuant to the foregoing Findings of Fact and Conclusions of Law:

It is hereby ORDERED this ___ day of _____, 2023 that ZHP's motion to seal parts of Fengitan Xue's expert report is DENIED.

/s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master